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No. -

In the Supreme Court of the United States

OCTOBER TERM, 1982

CORDIS CORPORATION,
PETITIONER,

v.

CARDIAC PACEMAKERS, INC.,
RESPONDENT.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

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I

Questions Presented

Did the District Court and the Court of Appeals err in including "secret" prior inventions within the prior art recognizable under 35 U.S.C. 103 or, equivalently, employing the "obviousness" standard of 35 U.S.C. 103 in determining anticipation under 35 U.S.C. 102(g)?

Did the Court of Appeals err in affirming holdings based upon "obviousness" when there was no evidence to support a factual finding regarding the level of skill in the art to which the invention pertained?

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PETITION

Petitioner, Cordis Corporation, respectfully prays that a Writ of Certiorari issue to review the judgment entered on October 12, 1982 by the United States Court of Appeals for the Eighth Circuit in its cause numbered 81-2048.

Opinions Below

The opinion of the court of appeals is reported at 690 F.2d 665. The district court's opinion is reported at 549 F.Supp. 564. Both opinions are reproduced in the accompanying Appendix.

* Cordis Corporation has as affiliates the following:
Cordis Europa, N.V.
Cordis Research Corporation
Cordis Laboratories, Inc.
Hyperion, Inc.
Norland Corporation
Cordis Dow Corp.

Jurisdictional Statement

The judgment of the court of appeals sought to be reviewed was entered on October 12, 1982. A timely petition for rehearing was denied on December 7, 1982. It is believed that jurisdiction is conferred on this Court by 28 U.S.C. §1254(1).

Statutes Involved

This matter involves the interpretation of Sections 102(g) and 103 of the Patent Act of 1952, both of which are reproduced in the accompanying Appendix.

Statement of the Case

Proceedings Below

The present action proceeds from a Declaratory Judgment action initiated by Cardiac Pacemakers, Inc. in Minnesota shortly after Cordis Corporation brought a patent infringement action in Massachusetts. Federal jurisdiction was predicated on 28 U.S.C. 1338(a). After the Massachusetts action was finally dismissed for lack of venue, *Cordis Corp.* v. *Cardiac Pacemakers, Inc.*, 599 F.2d 1085 (1st Cir. 1979), the present action went to trial. In a memorandum opinion dated August 31, 1981, Judge Devitt held that U.S. Letters Patent 3,805,796 was invalid based on prior art which included the secret prior inventions of third parties. That decision was appealed to the United States Court of Appeals for the Eighth Circuit which affirmed. Since the *per curiam* opinion of the Court of Appeals does not address the issue presented here, though it was extensively briefed, the opinions of both the District Court and the Court of Appeals are included within the Appendix accompanying this Petition.

The Invention

Cordis Corporation, the owner of the patent at issue here, manufactured and introduced to the practice of medicine the first programmable cardiac pacer. Introduced under the trade-

mark Omnicor, the design of this remarkable product provided significant advantages to both the patient and the manufacturer. As may already be understood by the Court, cardiac pacers are life sustaining devices which, in the absence of natural cardial activity, induce regular heart beating action by electrical stimulation. Understandably, reliable and predictable operation is of paramount importance.

The Omnicor pacer was programmable in the sense that a desired combination of operating parameters, *i.e.*, rate and the power of the output pulse, could be selected from a wide selection of values *after* the pacer was implanted. Such selection could, for the first time, be performed non-invasively and safely. Most importantly, inadvertent alteration of the selected values was rendered virtually impossible.

Programmability offered to the patient numerous advantages. An initial mis-selection of the rate or a change in the patient's condition requiring a changed rate could be corrected for without discomfort or risk of infection. Likewise, if the responsiveness of the heart to stimulation changed, for example, due to fibrotic growth around the stimulating electrode, the output power level could be changed so as to compensate.

Programmability also offers substantial advantages to the manufacturer of cardiac pacers. If only fixed parameter devices are possible, the manufacturer must have on hand devices providing a wide variety of rates and output pulse powers. Given the limited shelf life of the product, this inventory can represent a major cost of being in business.

Reese Terry and Gomer Davies, then employees of the defendant Cordis Corporation, devised a system of programming an implanted cardiac pacer which utilized, in the pacer, a magnetic reed switch operating in a rapidly pulsed mode, together with a pair of co-operating digital counters. Though incorporated into the implanted pacer, the reed switch was actuable by pulsing an electromagnet externally of the patient.

One of the pair of digital counters in the patented pacer circuitry operates as a memory to control the operating parameters of the pacer, *e.g.*, the pacer rate and the output pulse power, in accordance with the value held in the counter. In other words, if the counter could count up to a value of thirty two, then any one of thirty two different combinations of operating parameters could be selected by advancing the counter to the corresponding value.

Conscious of the dangers implicit in accidental reprogramming, Terry and Davies incorporated into their design a protection circuit or lock which prevented alteration of the value in the parameter counter except by the intended magnetic pulse signals. The other of the pair of digital counters is involved in this lock circuitry.

The programming and lock circuitry avoided accidental reprogramming in several ways. Firstly, the device was responsive only to externally generated pulse signals having predetermined characteristics. In particular, the pulses not only had to be magnetic so as to operate the reed switch but they also had to occur at a given rate or frequency. Secondly, before a pulse was allowed to affect the parameter control counter,a first group of pulses, an "address" or "safety" code, had to advance the lock circuitry counter to a predetermined value. Only after this first group of pulses was received was the parameter or memory counter reset and allowed to be advanced by subsequently received pulses. An important aspect of the invention was that a random single pulse could not reset or mis-program the implanted pacer. Thus, an accidental operation of the reed switch or a single electrical "noise" pulse could not disturb the desired parameter setting. If no pulses are received over a certain time interval, the lock counter is reset so as to be ready to test a new sequence of input pulses.

While the relatively simple lock scheme shown in the patent has proved to be extremely reliable in actual commercial prac-

tice, the inventors recognized that more elaborate address code schemes could be utilized and the original patent application language reflects that realization.

Although neither Herbert Lenzkes nor Robert Wingrove ever claimed to have made the same invention as the Cordis inventors, the trial court concluded the works of each of those men as part of the prior art within the meaning of 35 U.S.C. 103 even though those works were secret and not the subject of then pending patent applications.

Reasons for Granting the Writ

Among the technologically advanced nations of the world, the United States is unique in according rights to the first inventor as opposed to the first applicant for patent. The statutory provision which secures such rights for the first inventor, as against an earlier applicant, is Section 102(g) of Title 35 of the United States Code. The same right was accorded by Section 6 of the Patent Act of 1793.

To determine which of competing applicants was first, the Patent Office has long provided what is known as an interference procedure. This procedure provides for the gathering of evidence and a factual determination. The factual determination is performed initially by the Board of Patent Interference Examiners.

While the basic right of the "first inventor" has existed as long as the patent system in the United States, it is only comparatively recently that the "first inventor" facet of our law has been used as a defense in situations where neither interfering patent applications nor public use existed. The landmark case for this point of law was probably *Corona Cord Tire Co.* v. *Dovan Chem. Corp.*, 276 U.S. 358 (1928). For most of the intervening years, the Courts have narrowly constrained this defense, requiring not only that the alleged prior inventor must have reduced the disputed invention to

practice under strict evidentiary rules, but requiring also that the reduction to practice must have been of the "same" invention as that covered by the patent claim in question.

The precise extent to which this identity or "sameness" should be found in order to have "anticipation" under 35 U.S.C. 102(g) is not defined in any quantifiable terms by the statute itself. In interference proceedings in the Patent Office, the rule of law has developed that "immaterial" limitations in a patent claim may be ignored if the alleged prior invention otherwise meets the claim in all material respects, 37 CFR 1.205. In other words, a very high degree of sameness is required, though not absolute identity. By and large, the courts have employed a similar standard. As stated by the court in *Walker* v. *General Motors Corporation*, 362 F.2d 56 (9th Cir. 1966), at page 58,

> "anticipation is strictly a technical defense. Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference 'there is no anticipation' ".

Until recently, this precedent has been consistently followed. See *Ceramic Tilers Supply, Inc.* v. *Tile Council of America, Inc.*, 378 F.2d 283 (9th Cir. 1967), and was explicitly adopted by the Fourth Circuit in *Tights, Inc.* v. *Acme-McCrary Corp.*, 541 F.2d 1047 (4th Cir. 1976). See also the opinion of the Eighth Circuit in *Greening Nursery Co.* v. *J&R Tool and Mfg. Co.*, 376 F.2d 738 (8th Cir. 1967), at page 740,

> "The test for determining anticipation is whether the prior art discloses all the elements of the claimed combinations, or their mechanical equivalents, functioning in substantially the same way, to produce the same result."

More recently, however, imaginative practitioners have argued that prior inventions recognizable under 35 U.S.C. 102(g) constitute elements of the prior art which are recognizable under 35 U.S.C. 103. Under this view, such prior inventions, even if maintained in secrecy, would then be considered in combination with other elements of the prior art under the "obviousness" standard of 35 U.S.C. 103. As will be quickly understood, such a view completely emasculates the "sameness" requirement which had long been a prerequisite for anticipation under 35 U.S.C. 102(g). In fact, it almost completely obliterates or nullifies any distinction between the two statutory requirements, perverting the language and apparent legislative intent of the statute.

This broadened use of secret "prior invention" in defeating patents which would otherwise be valid under all knowable prior art has been the basis of considerable comment. See *The Defense Of Prior Invention, Patent Infringement Litigation* by Frank E. Robbins, published in 1977 by the Practicing Law Institute and also the article *Prior Art Under 35 U.S.C. Section 102(g)* by James B. Gambrell and Paul E. Krieger, published in the 1981 Patent Law Annual of the Southwestern Legal Foundation (Mathew Bender). The substance of this comment is that such expanded use of "secret" prior art will make the validity of patents wholly unpredictable.

It is the central theme of this petition that to include secret prior inventions within the prior art usuable under the "obviousness" standard of 35 U.S.C. 103 is improper and unsupportable and that, in the present litigation, the Courts below erred in adopting that proferred interpretation of the patent statute.

In a carefully reasoned decision, directly addressing the point of whether prior inventions recognizable under 35 U.S.C. 102(g) are part of the prior art recognizable under 35 U.S.C. 103, *In re Clemens, Hurwitz, and Walker*, 622 F.2d 1029 (CCPA 1980), the Court of Customs and Patent Appeals

explicitly held that such prior inventions are not part of the prior art under 35 U.S.C. 103. In explaining its holding, the Court noted, at p. 1039,

> "Where an applicant begins with knowledge of another's invention that will be available to the public at a later date as a result of an issued patent, treating this other invention as prior art is justified under facts such as those in *Bass*. No such consideration is present when the applicant does not begin with such knowledge. To the contrary, where this other invention is unknown to both the applicant and the art at the time the applicant makes his invention, treating it as 35 U.S.C. §103 prior art would establish a standard for patentability in which an applicant's contribution would be measured against secret prior art. Such a standard would be detrimental to the innovative spirit the patent laws are intended to kindle. Inasmuch as there are no competing policy considerations to justify it, as there is in the case of §102(e) prior art and lost counts, we decline to establish such a standard here."

This view was reconfirmed in that Court's decision in *In re Wertheim*, 646 F.2d 527 (CCPA 1981), where the Court said at page 537,

> "...we will extend the 'secret prior art' doctrine of *Milburn* and *Hazeltine* only as far as we are required to do so by the logic of those cases."

The *Milburn* and *Hazeltine* cases referred to relate to the treatment of pending applications as prior art, effective as of the date of filing. Such treatment prevents the state of the art from being impeded by the slowness with which the Patent Office necessarily acts. This treatment is now codified in 35 U.S.C. § 102(e). That situation is not involved here.

Rather than accepting the clear holding of the Court of Customs and Patent Appeals, Judge Devitt based his trial decision on the opinion of the 7th Circuit in *Sutter Products Co.* v. *Pettibone Mulliken Corp.*, 428 F.2d 639 (7th Cir. 1970). This opinion contains, at page 646, the statement,

> "Although *Hazeltine Research* dealt with the specific correspondence between Section 103 and Section 102(e), the considerations expressed are equally applicable to prior inventions under Section 102(g). (Citations omitted). The correspondence between the relevant 'prior art' under Section 103 therefore includes all material which would be considered to determine novelty under Section 102."

This statement is submitted to be in the nature of *obiter dicta* in that the Court had previously found, at page 647, the degree of sameness which was requisite under prior decisions,

> "So long as it embodies the same construction and principle as the alleged invention, a structure is effective as prior art even though the construction of the machine is crude, or the machine is imperfect in operation."

The initially quoted statement was thus unnecessary to the actual holding. Accordingly, as compared with the explicit *Clemens* holding, the *Sutter* case would seem an unsuitable precedent.

At this point, it seems appropriate to point out that this is not a new issue, that is, an issue developed in connection with this petition or even at the stage of appeal to the Eighth Circuit. Rather, this singular issue has been in the case from the very start. In his pre-trial brief, counsel for Cordis cited both the *Clemens* decision and the *Sutter* decision and devoted a substantial part of his argument to a reasoning, closely paralleling this petition, which urged that the *Clemens*

holding should be adopted. Notwithstanding this attempt to delineate this precise issue and to seek a reasoned decision on the point, the opinion of the trial court does not even acknowledge the existence of a contrary view. Though the point was briefed even more extensively on appeal, the opinion of the Eighth Circuit blandly states, "The applicable law is really not in dispute."

Not only is there a very real dispute as to the applicable law, but the resolution of the issue is determinative of the outcome of this litigation. Judge Devitt blurred the distinction between Sections 102(g) and 103 in each of his holdings regarding the validity of the Cordis patent. In his holding under 35 U.S.C. 103, he included, as elements of prior art, the alleged prior inventions of Lenzkes and Wingrove. Then, in his holding of anticipation under 35 U.S.C. 102(g), he employed the "obviousness" standard of 35 U.S.C. 103, ignoring admitted major differences in construction and principal of operation.

It may be noted that, in the present case, the differences are hardly "immaterial" since both the Lenzkes and Wingrove devices can be reprogrammed or disrupted by a single pulse, according to the uncontradicted testimony of those men themselves. As was brought out in both the trial and in the hearing before the Eighth Circuit, the function of the patented invention was to prevent mush disruption. However, with respect to this petition, the point being emphasized here is that the trial court is submitted to have used the wrong legal standard, that is, the trial court did not determine that Lenzkes and Wingrove made the "same" invention as the Cordis inventors.

In considering whether the holding in *Clemens* is properly applicable to the uncontroverted facts of the present case, it should also be clearly kept in mind that the supposedly earlier inventions of Lenzkes and Wingrove were in fact secret. At the time the invention in suit was made, the works of Lenzkes and

Wingrove were not the subject of patent applications nor were they known or knowable either to the Cordis inventors or to the hypothetical man of ordinary skill in the art.

If either of these men had previously made the "same" invention as the Cordis inventors, there may be valid policy reasons for invalidating the patent in suit, even though neither prior inventor ever claimed the Cordis invention. However, we submit that it is contrary to accepted standards of fairness and due process to include such secret works within the general fabric of prior art against which the invention is judged under 35 U.S.C. 103. That judgment is supposedly predicated on the standard of what would be obvious to one of ordinary skill in the art, assuming he was aware of the art. The conceptual flaw in including "secret" prior art is that this hypothetical man could not have been aware of the works of Lenzkes and Wingrove at the time the present invention was made.

Compounding the error in employing the "obviousness" standard of 35 U.S.C. 103 is the failure of the trial court to make a supportable determination regarding the level of skill in the art to which the invention pertains. Judge Devitt's opinion contains the statement that "CPI presented extensive expert testimony concerning...the level of ordinary skill in the art as of July 1, 1970...." This statement is palpably untrue. In appellant's main brief before the Eighth Circuit Court of Appeals, it was pointed out that Mr. Prohofsky (CPI's only expert at trial) gave *no testimony at all* regarding the level of skill in the art to which the invention pertained. This allegation was not even disputed by CPI in its brief or at the hearing. In fact, Prohofsky had expressly admitted at trial that he knew nothing about the cardiac pacemaker business prior to this litigation. His whole experience was in the digital computer field, not medical electronics. Judge Devitt apparently took his expansive view of the level of skill in the art and of the pertinent prior art solely because Cordis did not put on an expert in the field.

"CPI presented extensive expert testimony concerning the scope and content of the prior art, the level of ordinary skill in the art as of July 1, 1970, and the differences between the prior art and the Terry Patent claims. CPI's expert, Leroy Prohofsky, is an electrical engineer with extensive experience in microelectronics and circuit design techniques. We find that Prohofsky, by virtue of his skill, training, and experience was well qualified to testify on this subject. Cordis declined to call an expert witness to rebut Prohofsky's testimony (Trial Transcript, 711-12). In so doing, we reject Cordis' contention that the scope of the prior art be limited to biomedical implantable stimulators. The scope of the pertinent art in this instance includes the field of electrical engineering in general, and more specifically, the use of both digital and analog circuitry."

Although Counsel for Cordis emphasized to the Eighth Circuit Court of Appeals both the complete lack of supporting testimony and the requirement for a factual determination regarding the level of skill in the art under this Court's decision in *Graham* v. *John Deere Co.*, 383 U.S. 1 (1966), the appeal court's opinion was silent on this issue also.

A side issue to the "sameness" question is raised by the decision of the Patent Office not to institute any interference proceedings. Although the works of both Lenzkes and Wingrove, being secret, were raised as alleged "prior invention" rather than as prior applications for patent, both men did eventually file patent applications. Both of these applications, however, were filed later than the Terry et al. application, the application which issued as the patent in suit. Curiously, all three applications were, at one time, active cases under the jurisdiction of the same patent Examiner, Mr. William Kamm. Further, the file history of the Terry patent reveals that the Examiner, in his requisite interference search,

reviewed the classifications which contained the Lenzkes and Wingrove patent applications. The conclusion is almost inescapable that Mr. Kamm did not consider these applications to relate to the "same" invention. Still further, neither of the alleged prior inventors themselves ever claimed to have made the Terry invention, though both men were present at trial.

Conclusion

The attention of this Court to the singular issue presented by this petition is warranted for several reasons.

Firstly, the issue is determinative of the outcome of this litigation, a matter which was worth several million dollars at the time of trial. That sum continues to grow as CPI's production of admittedly infringing devices continues.

Secondly, the issue involves a novel interpretation of a statute of the United States by the lower courts.

Thirdly, the decisions of courts of appeal of the United States are in conflict and the writings of legal scholars illustrate the confusion which exists as to how the validity of a patent may be determined.

Respectfully submitted,

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